UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

KINETIC CONCEPTS, INC., ET AL.	§	
Plaintiffs,	§	
	§	**No. SA-08-CV-102-RF**
v.	§	
	§	
BLUESKY MEDICAL	§	
CORPORATION, and SMITH &	§	
NEPHEW, INC.,	§	
Defendants.	§	

ORDER GRANTING DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW OF INVALIDITY FOR OBVIOUSNESS

BEFORE THE COURT is Defendants Bluesky Medical Corporation and Smith & Nephew, Inc.'s (collectively referred to as "S&N") Motion for Judgment as a Matter of Law of Invalidity for Obviousness (Docket No. 504). A hearing was held in this matter on May 17, 2010. Having considered the arguments and filings by the parties and the applicable law, the Court GRANTS S&N's Motion for Judgment as a Matter of Law of Invalidity for Obviousness (Docket No. 504).

Background

The Plaintiffs in this action are Wake Forest University Health Sciences ("Wake Forest") Kinetic Concepts, Inc., KCI Licensing, Inc., Medical Holdings Limited, KCI Manufacturing, and KCI USA, Inc. (all Plaintiffs are collectively referred to as "KCI"). Wake Forest is the owner of U.S. Patents 5,636,643 ("the '643 patent"), 5,645,081 ("the '081 patent"), 7,198,046 ("the '046 patent"), and 7,216,651 ("the '651 patent") (collectively "the

Wake Forest Patents"). KCI is the exclusive licensees of the Wake Forest Patents.[1] KCI incorporates the technology of the Wake Forest Patents in its negative pressure wound therapy ("NPWT") product lines, namely, its Vacuum Assisted Closure® System ("V.A.C. System") which is used to care for difficult-to-treat and chronic wounds.

Pursuant to the patents, the V.A.C. System generally consists of four major components: (1) a vacuum pump; (2) tubing; (3) open celled foam; and (4) an adhesive seal. Tr. Trans. at 261-62; 269-70. After a wound is cleaned, the V.A.C. System is used to assist in the healing and closing of the wound. *Id.* at 274. First, the open cell foam is cut to fit the shape of the wound and placed inside the wound. *Id.* at 247-75. Then the adhesive seal is placed over the foam that is inside the wound. *Id.* One end of the tubing is placed through the seal into the foam and the other end is attached to the vacuum pump. *Id.* The vacuum pump is turned on and, because of the tight seal around the wound, the edges of the wound immediately begin to move together. *Id.* The use of the V.A.C. System over time promotes cell growth and the closing of the wound. *Id.* at 276.

A. Prior Litigation ("KCI I")

In 2003, KCI sued BlueSky Medical Corporation, Medela AG, and Medela, Inc. alleging that the gauze-based NPWT products produced by BlueSky infringed the '643 and

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[1] On July 8, 2010, Kinetic Concepts, Inc. and KCI Licensing executed sublicense agreements granting KCI Licensing an exclusive sublicense and an Addenda acknowledging the New Agreement was executed granting sublicenses to KCI Medical Resources, Medical Holdings Ltd., KCI Manufacturing and KCI USA. *See* Plaintiffs' Supplemental Complaint.

'081 patents. In its defense BlueSky and Medela argued the patents were invalid and unenforceable, or in the alternative, that its NPWT products did not infringe on the patents because their products were gauze-based and not foam-based. A jury found that the patents were not shown to be invalid, unenforceable, or infringed.

The jury's validity finding and the noninfringement finding were both ultimately affirmed by the Federal Circuit. *See Kinetic Concepts, Inc. v. BlueSky Med. Group, Inc.*, 554 F.3d 1010, 1025 (Fed. Cir. 2009). However, the Federal Circuit noted in its discussion that this Court committed harmless error by not instructing the jury on the construction of "wound" as used in the asserted patents. *Id.* at 1019. In its opinion the Federal Circuit stated that the wounds described in the specification of the patents were all skin wounds and "[t]o construe 'wound' to include fistulae and 'pus pockets' would thus expand the scope of the claims far beyond anything described in the specification." *Id.* Nevertheless, the Federal Circuit concluded that because the jury's verdict was supported under the proper construction, and because it perceived no danger under the circumstances of this case that the jury might have used an incorrect construction of "wound" that could have prejudiced Defendants, there was no need to remand for a new trial. *Id.*

Although the Federal Circuit did not expressly construe the term "wound" in its opinion, it is clear from the opinion that two factors were important to the correct construction of the term: first, that a wound be defined generally as an open skin wound. *See Kinetic Concepts, Inc.*, 554 F.3d at 1019; and second, that pus pockets, defined as an

enclosure below the skin such as a pocket of pus enclosed in a human breast, and fistulae be excluded from the definition. *Id.* at 1020. Based on this guidance by the Federal Circuit, the Court construed "wound" in the present litigation as "tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and excluding fistulae and pus pockets." *See* Claim Construction Order, Docket No. 280 at 6-8.

Following the jury's verdict and the entering of the final judgment, S&N acquired BlueSky Medical Corporation and its gauze-based NPWT products. In December 2008, S&N announced it would be launching a foam-based NPWT product. KCI filed the instant suit in December 2008 accusing BlueSky and S&N of infringing the Wake Forest Patents.

B. Present Litigation

The present case was tried to a jury in February 2010. At trial, KCI accused S&N of infringing the '081 and '651 patents (collectively the "patents in suit"). Specifically, KCI alleged that S&N's wound care products directly infringed Claims 2 and 5 of the '081 patent and induced infringement of Claims 42, 109, 116, and 121 of the '651 patent.[2] Claim 1 of the '081 Patent claims:

> An apparatus for facilitating the healing of wounds, comprising: vacuum means for creating a negative pressure between about 0.1 and 0.99 atmospheres on the area of skin including and surrounding the wound; sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said

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[2] Direct infringement of Claims 2 and 5 of the '081 patent necessarily includes infringement of Claim 1 and induced infringement of Claims 42, 109, 116, and 121 of the '651 patent necessarily includes infringement of Claims 108 and 20.

> wound; and screen means for positioning at the wound within the sealing means for preventing the overgrowth of tissue in the wound.

U.S. Patent No. 5,645,081 (filed July 8, 1997). In Claim 2 of the'081 Patent, the said screen means of Claim 1 is "an open-cell polymer foam" and in Claim 5 the sealing means of Claim 1 "includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin." *Id.*

KCI also argued that S&N induced infringement of Claims 42, 109, 116 and 121 of the '651 Patent. Infringement of these claims necessarily includes Claims 108 and 20. Claim 20 of the '651 Patent claims:

> A method for treating a wound, comprising: i. locating a flexible adhesive cover over the wound to provide a chamber between the cover and the wound, said cover adapted for maintaining reduced pressure at the wound; ii. adhesively sealing and adhering the periphery of said cover to tissue surrounding the wound; iii. operably connecting a vacuum system with said chamber at said seal for producing said reduced pressure; iv. interposing a fluid trap between said cover and said vacuum system; and v. maintaining reduced pressure to promote the formation of granulation tissue at the wound until the wound has progressed toward a selected stage of healing.

U.S. Patent No. 7,216,651 (filed May 15, 2007). Claim 108 of the '651 Patent claims "the method according to claim 20, comprising locating a porous material comprising a synthetic polymer under the cover at the wound." *Id.* Claim 42 of the '651 Patent claims:

> A method of treating a wound comprising the steps of: i. providing a vacuum source capable of providing at least 0.11 atm of reduced pressure; ii. locating a flexible adhesive cover over the wound, said cover having a suction port; iii. Locating a porous material comprising a synthetic polymer under said cover at the wound; iv. adhesively sealing and adhering the periphery of said cover

> to tissue surrounding the wound to form a continuous seal; v. operably connecting said suction port with said vacuum system for producing said reduced pressure; v. interposing a fluid trap between said suction port and said vacuum source; and vi. maintaining reduced pressure of at least 0.11 atm at the wound until the wound had progressed toward a selected stage of healing.

Id. Claim 109 of the '651 Patent claims "the method according to claim 42 or 108, wherein the porous material comprises foam" and Claim 116 of the '651 Patent claims "the method according claim 20, 42, or 108, wherein the wound comprises a pressure sore." *Id.* Finally, Claim 121 of the '651 Patent claims "the method according claim 20, 42, or 108, wherein the selected stage of healing comprises re-epithelialization of at least a portion of the wound." *Id.*

In response to KCI's allegations of infringement, S&N denied infringement of the asserted claims and also alleged that all of the asserted claims of the patents in suit were invalid as obvious under 35 U.S.C. § 103. In support of its invalidity defense of obviousness, S&N relied on numerous prior art references. The prior art references were generally divided into three primary categories—Bagautdinov, Zamierowski, and Chariker-Jeter. In the verdict form, S&N identified specific differences between the three primary categories of prior art and the asserted claims, and asked the jury to confirm that these were the only differences between the prior art and each claim. The jury did not agree and found that the prior art differences identified by S&N were not the only differences between the asserted claims and the prior art references. The jury was also asked to determine whether any secondary considerations had been established specifically for each claim. The jury found that most of

the secondary consideration factors had been established. Finally, the jury was also asked to rendered an advisory verdict on the ultimate legal conclusion of obviousness. The jury found that the claims would not have been obvious.

Applicable Law

A patent is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "Obviousness is a question of law based on underlying findings of fact." *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). The underlying factual inquiries include: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations, such as commercial success, long felt but unsolved needs, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

Here, the scope and content of the prior art and the level of ordinary skill in the art are not contested. The only disputed factual issues presented to the jury were the differences between the claimed invention and the prior art and the secondary considerations of non-obviousness. As stated above, the jury found that there were more differences between the claims and the prior art than S&N identified and that most of the secondary consideration factors had been established. In its Motion for Judgment as a Matter of Law, S&N argues

that substantial evidence does not support the jury's findings. S&N contends that because KCI's characterization of the prior art was inconsistent with the express teachings of the references and that because KCI did not connect its evidence of secondary considerations to the elements of the claims, KCI did not present evidence sufficient to overcome the showing of obviousness made by S&N. S&N argues that based upon this trial record, the Court should find that each of the asserted claims is invalid for obviousness, as a matter of law.

Pursuant to Rule 50(a)(1), judgment as a matter of law may be granted against a party if it "has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a). The Court "review[s] the jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 990 (Fed. Cir. 2009) (quoting *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1345 (Fed. Cir. 2008)). "While a jury may render a decision on a question of obviousness when it is considering any underlying fact questions, obviousness is ultimately a question of law that this court reviews *de novo*." *Id.* (citing *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997) (internal citations omitted). "When . . . , even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, [the Court] may reverse its obviousness determination." *Id.*

Discussion

A patent is presumed valid, and the burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity. 35 U.S.C. § 282 (2002). Invalidity must be proven by clear and convincing evidence. The Supreme Court has described "clear and convincing evidence" as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

As stated above, a patent may not be obtained if the differences between the claimed invention and the prior art would have been "obvious" at the time the invention was made to a person having ordinary skill in the art to which the patent is directed. *See* 35 U.S.C. § 103(a). The Supreme Court has emphasized that the obviousness inquiry is pragmatic and flexible: "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). Additionally, section 103 likely bars patentability if a person having ordinary skill in the art would have been able to implement a predictable variation of the prior art to yield the claimed invention. *Id.* at 417.

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 418. Where "there is a design need or market pressure to solve" a particular problem and there are only a discrete number of predictable solutions that lead to the anticipated

success of the patent, "[the patent] is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 421.

The Court, in evaluating the question of obviousness, finds that the only reasonable view of all of the evidence is that the claims in suit were obvious and that this was clear and convincing on the trial record. Therefore, for the reasons stated below, S&N's Motion for Judgment as a Matter of Law of Invalidity for Obviousness must be granted.

A. Scope of the Prior Art

At trial, S&N presented several prior art references. As stated above, the prior art references were generally divided into three primary categories—Bagautdinov, Zamierowski, and Chariker-Jeter. While the scope of these prior art references was not disputed, the Court will discuss the three primary categories of prior art to aid in its discussion of its finding of obviousness.

1. Bagautdinov Articles

The first category of prior art consists of two articles written by Russian doctor Nail Bagautdinov. The first Bagautdinov article ("Bagautdinov I") was published in 1986 in the Russian book Current Problems in Modern Clinical Surgery and is titled "Variant of External Vacuum Aspiration in the Treatment of Purulent Diseases of Soft Tissues." *See* Ex. P-1470. Bagautdinov I discusses "a method for vacuum treatment of primary and secondary purulent wounds." *Id.* at 3. The treatment for said wounds is described as follows:

> After surgical treatment of the purulent wound and hemostasis, a drain of polyurethane foam adapted in shape and size is placed on the surface (or in the

> cavity). The surrounding skin is smeared with sterile vaseline, antiseptic or inert salve on an oil base and covered with a polyethylene film. During localization of the purulent abscess on the forearm, shoulder, shin and thigh, isolation from the atmosphere is accomplished with a polyethylene sleeve which is attached to the skin on the periphery of the segment of the extremity distal and proximal to the wound with adhesive tape. For isolation of the hand, its fingers and the feet, polyethylene sacks of the corresponding size are used by attaching them, by a similar method, to the skin proximal to the wound. Regardless of the method of sealing, a tube is hermetically installed onto the foam through a hole in the polyethylene made beforehand. The latter is connected to the vacuum pump through a collection vessel. At a vacuum of 10 to 60 mmHg the film clenches the wound strictly along its skin boundaries with uniform vacuum treatment of the walls only on the side of the cavity and elimination of exudate because of the porous structure of the drain. The duration of the treatment sessions depends on the degree of vacuum and ranges from 30 minutes to 2 hours, whereupon the polyethylene is removed and a gauze bandage emplaced. The sessions are conducted daily until the wound is clean. On average this procedure takes 3 to 4 days.

Id.

The second Bagautdinov article ("Bagautdinov II") was written by Dr. Bagautdinov and Dr. Kuznetsov and published in 1986 as part of a Russian book containing multiple abstracts that was published and distributed at the II All-Union Conference on Wounds and Wound Infections in Moscow. *See* Ex. P-1471. The title of Bagautdinov II is "Vacuum and Vaccum-Sorption Treatment of Open Purulent Wounds." *Id.* Bagautdinov II describes the doctors' application of their developed methods of vacuum and vacuum-sorption treatment of purulent wounds and cavities on 170 patients. *Id.* at 14. The tested method is described as follows:

> Immediately after surgical treatment of the infected area in the commonly accepted manner or using a Scalpel-1 laser, a drain made from polyurethane foam is placed in the wound. For sorption treatment, it is first

> filled with activated charcoal powder. The wound is sealed with polyethylene film in one of several ways, depending on the localization of the purulent focus. Vacuum aspiration is conducted through an aspiration tube using a constant suction pump. Thus, the polyethylene film "clenches" the wound strictly along its edges, and the sorbent makes secure contact with the walls. The porous structure of the drain allows for removal of exudate and vacuumization of the wound only from the cavity side. The session lasts 1-2 hours with negative pressure of 10-40 mmHg, after which the isolation is removed. The drain is changed 1-2 times daily.
>
> Vacuum treatment was continued for 3-4 days.

Id. at 14-15.

Dr. Bagautdinov testified at trial that he developed his vacuum system described above "to use -- over the walls of a wound using negative pressure, and at the same time distributing negative pressure, being able to distribute this negative pressure from the cavity itself only, and promoting healing of the wound by resolving and focusing on inflammatory infection stage of healing process." Tr. Trans. at 2160.

2. Zamierowski Patent Cooperation Treaty Application

Defendants also presented, as prior art, Dr. David Zamierowski's International Application Published Under the Patent Cooperation Treaty ("Zamierowski PCT Application"). *See* Ex. P-1070. The Zamierowski PCT Application was filed on April 3, 1990. *Id.* at 1. The application states that it is a "Continuation-in-Part of U.S. Patent Application Serial Number 07/332,699, filed April 3, 1989." *Id.* at 3. The Zamierowski PCT Application describes an invention that "relates generally to fluidic connection systems, and in particular to systems for draining liquids from and introducing liquids to patients." *Id.*

Dr. Zamierowski has received multiple patents related to his fluidic connection systems and in the early 1990s KCI purchased those patents from Dr. Zamierowski and incorporated his invention into the their V.A.C. System. *See* Tr. Trans. at 2569-70.

The following is the summary of Dr. Zamierowski's invention which was part of his PCT Application that was presented as prior art at trial.

> In the practice of the present invention, a fluidic connection system is provided which includes a semipermeable membrane including a pair of panels each having a perimeter and an edge strip. The membrane is formed by connecting the panel edge strips together to form a seam extending transversely across the membrane. The panels and the membrane include inner and outer surfaces. A tube opening extends through the seam between the panel edge strips and between the membrane inner and outer surfaces. The membrane inner surface is coated with an adhesive for attachment to the skin of a patient.
>
> A tube or sheath includes a proximate end extending through the tube opening and a distal end positioned in spaced relation from the membrane outer surface. In one embodiment, the tube proximate end includes a side opening which is positioned in proximity to the membrane inner surface. In another embodiment the tube proximate end is bifurcated by a pair of longitudinally-extending slits separating a pair of tabs. A passage extend through the sheath between its ends.
>
> An inner conduit can be placed in the sheath passage and can include a connection seal assembly for forming a fluid-tight seal with the sheath. The inner, tubular conduit can be provided with a funneled proximate end for using the system as a condom catheter.
>
> When the fluidic connection system is used as a wound dressing, an intermediate layer of material can be applied between the wound and the cover membrane inner surface. Furthermore, the fluidic connection system of the present invention can be used to secure a percutaneous drainage tube within a patient, e.g. by inserting the percutanious tube through the sheath passage.
>
> In the practice of the method of the present invention, an intermediate layer of material can be applied to a wound site and the cover membrane can then be placed thereover. The cover membrane can be releasably, adhesively fastened to the skin around a periphery thereof. A tube fluidically communicates with the wound through an opening in the membrane. Fluids

> from a draining wound can be evacuated through the tube and liquid medication and irrigation can be introduced through the tube to the wound site. The fluid evacuation and introduction steps of the method can each be accomplished both actively and passively, and can be alternated in a wound treatment procedure. Additional steps that can be included in the method of the present invention include extending an inner conduit through the sheath and sealing the inner conduit and the sheath together in a fluid-tight engagement.

Ex. P-1070 at 5-7.

3. Chariker-Jeter Articles and Public Use

The third major category of prior art presented at trial is collectively referred to as the "Chariker-Jeter" prior art. The Chariker-Jeter prior art consists of two articles published by Dr. Mark Chariker and Dr. Katherine Jeter,[3] and Dr. Chariker's 1989 public use of the system described in the Chariker-Jeter articles.

The first Chariker-Jeter article ("Chariker-Jeter I") was written by Dr. Chariker, Dr. Jeter, Dr. Tess Tintle, and Dr. John Bottsford and published in Contemporary Surgery in 1989. *See* Ex. P-1451. Chariker-Jeter I is titled "Effective management of incisional and cutaneous fistulae with closed suction wound drainage." *Id.*; Tr. Trans. at 2009-10. Chariker-Jeter I describes the doctors' "closed suction wound drainage system" that they devised to treat patients with ventral incisions complicated by enterocutaneous fistula. *See* Ex. P- 1451 at 1. Dr. Chariker explained at trial that "[a] 'fistula' is an abnormal connection between one body part to the other" and that "entero" means bowel and "cutaneous" means skin, therefore,

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[3] Dr. Jeter is not a medical doctor. She has a doctorate in education and human development from George Washington University in Washington, D.C. Tr. Trans. at 2088. Dr. Jeter is trained in enterostomal therapy. *Id.* at 2093.

the wounds that Chariker-Jeter I is referring to are complicated by an abnormal connection between the bowel and the skin. *See* Tr. Trans. at 2008-09.

Chariker-Jeter I explains that its closed wound drainage system is created in the following manner:

> 1) Irrigate wound bed thoroughly with normal saline via a 30ml syringe with a 19-gauge needle.
>
> 2) Open completely one two by two inch square. Lay this across the wound bed.
>
> 3) Place Jackson-Pratt drain in wound bed. Shorten the fenestrated drain as necessary so that the flat drain is confined to the wound bed. (The drain is never placed into the fistula tract)
>
> 4) Open four by four inch gauze squares. Saturate with normal saline. Fluff into wound to completely cover the drain and fill the defect to skin level.
>
> 5) Apply skin sealant to all skin that will be covered by transparent adhesive film dressing. Allow to dry until slick.
>
> 6) Cut transparent adhesive film dressing or select size to allow at least one inch of intact skin beyond wound edges. Place film dressing over packed wound. Split one end of the film dressing sheet in order to bring each "arm" around the Jackson-Pratt tubing. Crimp the edges of the film dressing around the tube.
>
> 7) At tube exit site, squeeze a small amount of Stomahesive Paste where film dressing meets tube to seal an air-tight closure.
>
> 8) Reinforce this juncture with pink tape as illustrated.
>
> 9) Turn your attention to the connection of the Jackson-Pratt tube to continuous suction system. A small "Christmas tree" connector is ideal to connect the end of the drain to the wall suction tubing. (Do not attempt to use the bulb of the Jackson-Pratt system unless you are transporting the patient for a short period of time.) If you cannot locate a small "Christmas tree" connector, you can cannabilize IV tubing to get a small plastic adapter.
>
> 10) Turn on continuous suction to the upper range of the low setting, approximately 60-80mmHg, and observe the wound site. The dressing should contract noticeably. If it does not, you do not have a closed system and wound drainage will override it.
>
> Critical to the efficacy of our system is the moist gauze packing in the wound. This packing obliterates the dead space known to be an impediment to wound closure, and it is an imperative component in the suction system.

Ex. P-1451 at 2.

The second Chariker-Jeter article ("Chariker-Jeter II") was written by Dr. Jeter, Dr. Tintle and Dr. Chariker and published in Chronic Wound Care: A Clinical Source Book for Healthcare Professionals in 1990. *See* Ex. P-1083. Chariker-Jeter II is titled "Managing Draining Wounds And Fistulae: New And Established Methods." *Id.*; Tr. Trans. 2010. Chariker-Jeter II describes the same "closed suction wound drainage system" that is intended "to enhance management of incisional and cutaneous fistulae," but provides the following more detailed instructions on how to create the system:

1. Irrigate the wound bed thoroughly with normal saline using a 30 ml syringe with a 19-gauge needle.
2. Moisten one 2X2 gauze square with normal saline. Open completely and lay across the wound bed.
3. Place Jackson-Pratt drain in wound bed. Shorten the fenestrated drain as necessary so that the flat drain is confined to the wound bed. *The drain is never placed in the fistula tract.* In the case of fistula drainage at skin level, the fenestrated portion of the drain is simply centered over the cutaneous opening. It may be helpful to encircle the cutaneous wound with a pectin-based skin barrier in order to create a "trough" in which to situate the fenestrated drain.
4. Saturate 4X4 gauze squares with normal saline. Open and fluff into wound to completely cover the drain and fill the defect to skin level. In the case of a cutaneous fistula, only enough moist gauze to cover the flat fenestrated drain is required.
5. Apply skin sealant (Bard Barrier Film, Skin-Prep, etc.) to all skin that will be covered by the film dressing. Allow to dry until slick.
6. Cut the film dressing or select a size to allow at least 1 inch of intact skin beyond the wound edges. Place the film dressing over the packed wound. Carefully crimp the adhesive film dressing around the Jackson-Pratt tube to seal.
7. "Caulk" the tube exit site with a small amount of Stomahesive Paste where the film dressing is crimped around the tube. This ensures air-tight closure.
8. Reinforce this site with waterproof "pink tape" as illustrated.

9. Turn your attention now to the connection of the Jackson-Pratt to continuous suction. (Do not attempt to use the bulb of the Jackson-Pratt system.) With some brands of cannister and tubing, all that is necessary is to cut the funnel end off the tubing and the small J-P tubing will fit snugly into the larger lumen tube. The junction should be taped securely with pink tape. Otherwise you may use small "Christmas tree" connector or cannibalize IV tubing to get a small plastic adapter to connect the tubing.
10. Turn on continuous suction to the upper range of the low setting (approximately 60 to 80 mmHg) and observe the wound site. The dressing should contract noticeably. If it does not, the system is not closed and wound drainage will not be efficiently removed. When this occurs, fistula drainage will accumulate, causing skin damage and leakage outside of the dressing. Another indication that you have not obtained a closed suction system is a whistling sound indicating that the dressing is not air-tight.

See id. at 5.

S&N also presented as prior art the 1989 public use of the Chariker-Jeter closed suction wound drainage system on Mr. Gary Aderholt. Mr. Aderholt was a patient that came into Dr. Chariker's trauma service in 1989. Dr. Chariker testified that "[Mr. Aderholt] was injured with a log chain that flew off another truck into his truck, entered his chest, his abdomen, ruptured his lung, his [diaphragm], his pancreas, his spleen, his stomach." Tr. Trans. at 2032. The closed wound suction system was placed in Mr. Aderholt's mid abdomen with the objective of trying to close his abdomen and put the bowel contents back into abdomen. *Id.* at 2037. S&N presented pictures that chronicled Mr. Aderholt's healing progress and ended with pictures of his completely healed abdomen. *See* Exs. P-1058, P-1483. S&N presented the public use of Mr. Aderholt as an example of the Chariker-Jeter closed suction wound drainage system being used to facilitate the healing of a wound on a patient without a fistula. *See* Tr. Trans. at 2085 ("[Question]. And anywhere in all the

diagnoses of Mr. Aderholt, is it ever, ever suggested by any physician, attending, resident, intern, nurse, any hospital care worker, that Mr. Aderholt had a fistula? [Answer]. No, sir. It's not in there.").

B. Differences Between the Prior Art and Asserted Claims

"[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, 127 S.Ct. at 1740 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). The jury verdict form presented the jury with what S&N considered to be the only differences between the asserted claims and the three primary categories of prior art. Specifically, the jury was asked to answer the following question for each prior art category:

> Did Smith & Nephew prove that it is highly probable that the following are the only differences between the [prior art category], and the following claims? Answer YES or NO for each claim.

See Jury Verdict Form, Docket No. 497 at 5-9.

The jury answered "no" for all fifteen sub-parts, apparently finding that there were additional differences between the prior art and the asserted claims than the differences listed by S&N. However, after reviewing the prior art as a whole the Court finds that the differences between the claimed invention and the prior art, if any, are minimal.

The asserted claims generally teach the use of four components as a method for facilitating the healing of wounds, (1) a vacuum pump; (2) tubing; (3) open celled foam; and

(4) an adhesive seal. *See* Claims 1, 2, and 5 of the '081 patent; Claims 20, 108, 42, and 109 of the '651 patent. These four components are clearly taught in the prior art. For example, the Bagautdinov references teach placing foam in a wound, sealing the wound, using tubing to connect a vacuum pump through the seal to the foam, and using negative pressure to heal the wound. *See* Ex. P-1470 at 3. The major difference between the Bagautdinov system and the claims asserted, namely the differing method for sealing the wound, is disclosed in the Zamierowski prior art. In fact, the Zamierowski prior art was actually incorporated into the V.A.C. system as the basis for the V.A.C. System's sealing means. At trial, Dr. Zamierowski explained through his deposition testimony how his patents contributed to the development of KCI's V.A.C. system. His testimony was a follows:

> Q. What part of your patents would you say are included in the VAC?
>
> A. There's a theme through this patent portfolio that we mentioned already, and that's fluidic connections. That is such a broad topic and a broad mechanical field. There are entire textbooks about fluidic dynamics. If we tried to narrow that down, I think my patents and my contribution to the VAC are primarily concerned with the methods of attaching the rigid conduit to the flimsy film.
>
> . . . .
>
> Q. Are there any similarities between the VAC and the apparatuses described in the '880 Patent?
>
> A. The VAC dressing uses a cover layer and intermediate layer, addresses treatment of wounds, open tissue, uses a conduit and vacuum, it addresses the actions of wound care of drainage. And those are the similarities with the '880 Patent which also lists cover and intermediate layer of wound, the management of drainage, and the use of active evacuation with vacuum.

> Q. Okay. Are there any differences between the VAC and the '880 Patent?
>
> A. I'm -- I feel the '880 Patent contributes to the VAC, so it's a part of the VAC presentation, not a difference from the VAC.

Tr. Trans. at 2571-72.

Accordingly, after reviewing the prior art, the Court finds that the method and apparatus for healing wounds taught by the asserted claims in this case are disclosed by the prior art presented at trial. While each prior art reference has some difference from the asserted claims, the differences are minimal.

However, the jury found that the differences identified by S&N between the prior art and the asserted claims were not the only differences. Plaintiffs argue that because the jury was not asked to identify the particular additional differences that exist, the jury is presumed to have found that the prior art differs in all the ways asserted by Plaintiffs that are supported by substantial evidence. *See Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999). Plaintiffs argue that there are many differences supported by substantial evidence and that the Court must presume the jury found those differences. *See* KCI's Response Brief, Docket No. 526 at 7-21. However, after reviewing the record, the Court can identify only one significant additional difference presented by KCI at trial, which was that the Bagautdinov, Zamierowski, and Chariker-Jeter prior art did not facilitate the healing or provide a method for treating "wounds" as defined by the Court.

As mentioned at the outset, the Court construed the term "wound" to mean "tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and

excluding fistulae and pus pockets." KCI consistently argued both at trial and in their response to S&N's Motion for JMOL of Invalidity for Obviousness that: (1) Bagautdinov differs from the claims asserted because it treats purulent wounds which are excluded by the Court's definitions; (2) Zamierowski is merely a device designed to introduce liquids to or drain liquids from a dressing placed on patients with surgical wounds and does not actually "treat" a wound; and (3) the Chariker-Jeter prior art deals solely with managing fistulae not "treating wounds"as defined by the Court. These arguments have no support in the evidence, however.

1. Bagautdinov

Specifically, KCI argues that the Bagautdinov prior art differs from the claims asserted because, although Bagautdinov teaches placing polyurethane foam in the wound cavity, sealing the wound, and connecting a tube from the foam to a vacuum source, it treats purulent wounds and, because purulent wounds are associated with pus, they are excluded from this Court's definition of "wound." KCI also argues that Dr. Bagautdinov admitted that he only used his technique to treat infected, or pus-filled, wounds, not uninfected traumatic wounds, similar to those claimed in the inventions. *See* KCI's Response Brief, Docket No. 526 at 14; Tr. Trans. at 2312. KCI further argues that S&N's expert Dr. Gordon admitted that he interpreted the Bagautdinov references to deal solely with patients who had purulent disorders that needed to be drained. *See* KCI's Response Brief, Docket No. 526 at 14; Tr. Trans. at 2429-31. Additionally, KCI argues that their expert Dr. Orgill opined that

Dr. Bagautdinov was not treating a wound because his references discuss "purulent diseases" which in his opinion are pus pockets that are excluded from the definition of wound. *See* KCI's Response Brief, Docket No. 526 at 13; Tr. Trans. at 2735-36. KCI consistently dismisses the Bagautdinov references because the wounds they treat are "purulent," "pus-filled" or "associated with pus" which KCI equates with the excluded "pus pockets." *See* KCI's Response Brief, Docket No. 526 at 13-16.

As mentioned above, the definition of "wound" came from the Federal Circuit's opinion in KCI I, where it was determined that a pus pocket is not a wound but rather is akin to an enclosure within a human breast. A pus pocket is thus an enclosed cavity with pus under the skin instead of an open skin wound. This distinction marks the clear difference between a wound and a pus pocket, a distinction which must be observed so that the scope of the claims is not improperly narrowed beyond anything described in the specifications of the patents in suit. In KCI I, the concern was that the scope of the claims might be expanded too far. *See Kinetic Concepts Inc.*, 554 F.3d at 1019. Here, the converse is the problem because KCI now argues that the scope of the claims should be unduly narrowed to cover only a subset of wounds described in the specifications. The argument not only excludes pus pockets from the definition of wounds, but it also excludes infected wounds or wounds with pus from the definition of wounds.

Utilizing such a construction, KCI argues that the Bagautdinov references have no application to the patents in suit because the references only treat "infected, or pus-filled

wounds" and not the "uninfected traumatic wounds similar to those in the claimed invention." KCI's Response Brief, Docket No. 526 at 14. The Court observes at least two problems with this argument. In the first place, KCI's assertion that the claimed invention refers only to "uninfected traumatic wounds" flies in the face of the descriptions in the patents in suit. For example, the abstract of the '081 patent specifically states that "[t]he method is applicable to wounds, burns, *infected wounds*, and live tissue attachments." U.S. Patent 5,645,081 (emphasis added). Additionally, the summary of the invention states that "[a] preferred use of this method is its application to a wound for at least 3 days to reduce the bacterial density of an *infected* wound to the point at which surgical closure can be attempted." *Id.* (emphasis added). In the '651 Patent an example is given of using the apparatus claimed in the patent on patients with "an *infected* left trochanteric pressure sore" and "bilateral 10 cm by 15 cm *infected* ulcers with exposed fascia." U.S. Patent No. 7,216,651 (emphasis added). A definition of wound that excludes tissue damage to the skin involving pus or infection is therefore not supported by the patents themselves.

In the second place, KCI's argument that Bagautdinov only treats pus pockets, not wounds, is a misreading of the references. It is clear that the Bagautdinov prior art treats wounds, whether purulent or not. Bagautdinov I states that "[a]fter surgical treatment of the purulent *wound* and hemostasis, a drain of polyurethane foam adapted in shape and size is placed *on the surface* (or in the cavity)." Ex. P-1470 at 3 (emphasis added). Additionally, Bagautdinov II states "[i]mmediately after surgical treatment of the infected area in the

commonly accepted manner or using a Scalpel-1 laser, a drain made from polyurethane foam is placed in the *wound*." Ex. P-1471 at 14 (emphasis added). A wound with or without pus is still a wound, not a pus pocket.

Without question, the patents in suit are intended to treat *open* skin wounds, which is why the Court followed the guidance of the Federal Circuit that the patents are not intended to treat "pus pockets," which signify pouchlike closed cavities. As noted above, it is also without question that the patents in suit are intended to treat all kinds of skin wounds, including infected wounds or wounds with pus. Accordingly, KCI's effort to distinguish this prior art by conflating an infected wound with a pus pocket impermissibly blurs the separation between the two concepts.

If the Court were to accept KCI's argument that an infected wound or wound with pus constitutes a pus pocket, the patents in suit would cover only wounds without pus or infection. Yet, what if it is not clear whether a particular wound has pus or an infection? Whether to utilize the patented invention would therefore be equivocal, with the ambiguity making it impossible from a practical viewpoint to determine the boundaries of the patents themselves. Under such circumstances, Bagautdinov cannot be so distinguished from the patents in suit and KCI's attempt to do so must fail, as a matter of law. Therefore, KCI's argument that a pus pocket is any wound with pus, excluded from the ambit of the patents in suit, renders the patents meaningless because it obscures the contours of the basic invention.

Accordingly, the Court finds, after evaluating the Bagautdinov references, that they describe the treatment of open skin wounds whether infected or not.[4] The references teach placing polyurethane foam inside or on the surface of the wound and report that the wounds "healed" because of the development of granulation tissue.[5] Pus pockets or the treatment of any kind of pouchlike closed cavity are not mentioned in the references. Accordingly, the Court finds that there is substantial evidence to support that the Bagautdinov prior art references treat or heal "wounds" as defined by the Court.

Thus, the Bagautdinov references teach a method for healing wounds that consists of inserting foam into a wound, sealing the wound with polyethylene film, connecting the foam to a vacuum pump using a tube and activating the vacuum pump so that the polyethylene film "clenches" the wound strictly along its edges. Differences, if any, between the claims asserted and the Bagautdinov references are minimal.

2. Zamierowski

S&N asserted at trial that the only differences between the claims asserted and the Zamierowski reference were that in Zamierowski the specific negative pressure range was not specified and that the vacuum system in Zamierowski was connected through a slit in the top of the cover rather than at the seal with the skin. The jury did not agree that these were the only differences. KCI argues that several additional differences exist between the

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[4] Ex. P-1470 at 3; Ex. P-1471 at 14.

[5] Ex. P-1470 at 3-4; Ex. P-1471 at 14-15.

Zamierowski reference and the claims asserted that the Court must accept as implied findings of the jury. However, as stated above, the Court can identify only one significant additional difference presented by KCI at trial, namely that the Zamierowski prior art did not facilitate the healing or provide a method for treating wounds.

It is undisputed that Zamierowski discloses placing a screen means such as foam into a wound, sealing the wound by placing a membrane with an adhesive coating over the wound, and connecting a tube from under the membrane into a vacuum source and activating the negative pressure. *See* Tr. Trans. at 2350; S&N's Motion for JMOL, Docket No. 504 at 14. Additionally, unlike the Bagautdinov and Chariker-Jeter prior art, KCI also concedes that the Zamierowski method is used on wounds as defined by the Court. However, KCI argues that Zamierowski is different from all the asserted claims because it fails to disclose treating or facilitating the healing of wounds *with negative pressure*. *See* Tr. Trans. at 2667-70; KCI's Response Brief, Docket No. 526 at 18-19. KCI asserted both at trial and in its response to the instant motion that rather than actively treating the wounds through negative pressure like the asserted claims, the Zamierowski reference teaches facilitating the healing of wounds by adding liquid medications or growth factors to a wound through the single ingress/egress tube or by removing liquid from a wound and thereby promoting "natural healing" by preventing infection. *Id.* at 19; Tr. Trans. at 2670. Therefore, while KCI acknowledges that Zamierowski teaches healing wounds, it distinguishes the healing provided by Zamierowski as merely "natural healing" or "passive healing" that is the result

of drainage of the wound and not the result of applying and maintaining negative pressure.

KCI's argument that Zamierowski does not disclose the treatment of wounds with negative pressure, as claimed by the patents in suit, fails for two reasons. First, such a narrow definition of treating or healing wounds is not disclosed in the asserted claims. KCI's argument draws a distinction between "active" healing or treatment, which it argues is disclosed in the patents in suit, and "passive" or "natural" healing or treatment which it argues is taught by Zamierowski. But such a distinction is not present in the asserted claims, nor was one construed by this Court. The asserted claims simply disclose "an apparatus for facilitating the healing of wounds" or "a method for treating a wound," which Zamierowski is clearly intended to do. *See* Ex. P-1070 at 3 (stating that the Zamierowski "[w]ound dressings are typically applied over various types of wounds to promote healing and to reduce the risk of infection").

Second, even if the Court were to agree that the claims asserted require that the wound treatment be derived from the application of negative pressure, Zamierowski discloses such wound healing. While the primary focus of Zamierowski might be drainage, it is clearly disclosed in Zamierowski that the drainage can be done actively by connecting the tube inserted into the wound into a vacuum source and using negative pressure to remove fluid from the wound. *See* Ex. P-1070 at 7, 13-14. Even KCI's expert acknowledged that removal of fluids from a wound operates to heal a wound. Tr. Trans. at 2670 (noting that by removing liquid from the body "you don't get the problem with maceration or infection that

people got before" and it helps the body naturally heal). Accordingly, by removing the fluid from the wound using a vacuum suction, the Zamierowski reference discloses healing a wound through application of negative pressure.

Additionally, KCI argues that Zamierowski fails to disclose any promotion of granulation tissue toward a selected state of healing, thereby asserting that Zamierowski does not disclose the treatment or healing of wounds as disclosed in all of the asserted claims. *See* KCI's Response Brief, Docket No. 526 at 19; Tr. Trans. 2456-58. While Zamierowski does not specifically mention the promotion of "granulation tissue," Zamierowski does disclose the use of its method to assist in the *closure* of skin graft donor sites. *See* Ex. P-1070 at 11. (noting that "the wound dressing and treatment method of the present invention is particularly well adapted for the protection and regeneration of skin graft donor sites"). It stands to reason that said closure would necessarily require the promotion of "granulation tissue" as defined by the Court, "tissue formed during wound healing." *See* Claim Construction Order, Docket No. 280 at 37. Also, the Court notes that the asserted claims do not disclose the actual formation of granulation tissue, but the *promotion* of the formation of granulation tissue. After reviewing the Zamierowski reference, it is clear that the method disclosed would *promote* the tissue formed during wound healing.

As far as disclosing a selected state of healing, Zamierowski discloses that its method is particularly useful during the "fluid drainage phase of the healing process." Ex. P-1070 at 18. As stated above, the removal of fluids from a wound is a stage of healing. *See* Tr.

Trans. at 2670. While the actual stage of healing reached by the asserted claims may be closer to full closure of the wound than the stage achieved by Zamierowski, such a specific stage is not disclosed in the patents. Accordingly, it cannot be argued that Zamierowski does not promote the tissue formed during wound healing toward a particular stage of healing because the Zamierowski method is not used to reach the same stage of healing as the asserted patents. Therefore, because removing fluid from a wound is the first step toward tissue growth, even if all the Zamierowski method is doing is draining fluid from the wound, it is promoting tissue growth in the wound until the wound has progressed through the fluid drainage stage of healing.

Also, the formation of granulation tissue or a selected stage of healing is only one limitation in a few asserted claims. *See* Claims 20 and 42 of the '651 patent. Therefore, even if Zamierowski did fail to disclose the promotion of granulation tissue or a selected stage of healing, it would only differentiate Zamierowski from those particular claims, not all asserted claims. It is not necessary in an obviousness determination that all the limitations of an applicant's claim appear in a single prior art reference.

Zamierowski discloses healing and treating wounds by placing foam in a wound, sealing the wound with an adhesive sheet, and inserting flexible tubing from the wound to a vacuum source. In fact, as discussed above, KCI actually purchased the Zamierowski patents and incorporated the invention into its V.A.C. System. Dr. Zamierowski himself noted that his invention "contributes to the VAC, so it's a part of the VAC presentation, not

a difference from the VAC." Tr. Trans. at 2571-72. Accordingly, the Court acknowledges that variations between Zamierowski and the asserted claims exist, but finds that those differences are minimal in light of the many similarities in connection with an obviousness determination.

3. Chariker-Jeter

Like the Bagautdinov prior art, the only substantial additional difference between the asserted claims and the Chariker-Jeter prior art presented at trial was that the Chariker-Jeter prior art deals solely with managing fistulae not "treating wounds"as defined by the Court. As discussed above, the Federal Circuit considered the Chariker-Jeter prior art when reviewing KCI I. In its opinion on KCI I, the Federal Circuit "agree[d] with KCI that 'wound,' as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications." *Kinetic Concepts, Inc.*, 554 F.3d at 1018. Additionally, the Federal Circuit held that even though there was testimony presented about the use of the Chariker-Jeter method on a patient whose wound did not include a fistula, there was sufficient evidence presented at trial to allow the KCI I jury to reach the conclusion that the Chariker-Jeter method was not used to "treat a wound with negative pressure" as required by the claims. *Id.* at 1020.

However, after reviewing the record from the present litigation, the Court finds that there was not sufficient evidence presented at trial to allow the Court to accept an implied finding by the jury that the Chariker-Jeter method is not used to treat a "wound" as defined

by the Court. To adopt such a finding would ignore the Chariker-Jeter system's clearly stated purpose of treating wounds *complicated* by a fistula. *See e.g.*, Ex. P-1451 at 4 (stating two basic problems in "wounds complicated by draining enteroeutaneous fistulae"); *see also* Tr. Trans. at 2044-46. It is clear from the references that the Chariker-Jeter system is used in treating both the open wound and the complicating fistula. *See* Ex. P-1451 at 1 ("We believe this conformation and the effectiveness of the continuous closed suction are critical to fistula closure and wound contraction."); *see also* Ex. P-1083 at 9 (discussing the benefits of the closed suction wound drainage system as being "fistula closure with optimal wound healing").

In fact, when discussing the patients that were treated with the Chariker-Jeter system, the reference discusses the closure of the fistula and the closure of the wound separately. *See* Ex. P-1451 at 4 ("In the case of our renal fistula patient . . . . Once the fistula closed, the flank healed rapidly, the wound contracted, and a small scar remains."); Ex. P-1083 at 7 (describing the same patient). While drainage of the fistula effluent may be the primary purpose of the Chariker-Jeter system, it is clear from the references themselves that the ultimate goal of the system is to aid in both closure of the fistula and the ultimate closure of the wound. *See id.* at 4-5 (stating that the Chariker-Jeter system "contributes to wound closure by second intention" and connecting the continuous removal of effluent to the increased rate of reepithelialization and wound contracture).

Additionally, the argument that the Chariker-Jeter system is only used to treat fistulae

and not "wounds" as defined by the Court completely disregards the public use prior art presented at trial. As stated above, S&N presented as prior art at trial the public use of the Chariker-Jeter system on a patient, Mr. Aderholt, who had an open wound that was not complicated by a fistula. Dr. Chariker testified that he used the closed suction system on Mr. Aderholt's abdomen, and specifically he stated that he put gauze in the wound, connected the suction tubes from the gauze to the vacuum source, and then covered the entire area with the adhesive dressing. Tr. Trans. at 2035-36; *see also* Ex. P-1058 (pictures of Mr. Aderholt's progress throughout treatment). Dr. Chariker testified that his objective in using the closed suction system was to close Mr. Aderholt's abdomen. Tr. Trans. at 2037.

KCI argued during its cross examination of Dr. Chariker that the injury to Mr. Aderholt's pancreas, which is located behind all the abdominal contents, might have been described as a fistula by other doctors. Tr. Trans. at 2057. KCI presented the testimony of its expert, Dr. Orgill, who opined that Mr. Aderholt's treatment did involve the treatment of a fistula. *See* Tr. Trans. at 2711. However, such a conclusion was completely unsupported by the evidence. Dr. Chariker consistently stated that Mr. Aderholt was never diagnosed with a fistula. *See* Tr. Trans. at 2055-58 ("Didn't Mr. Aderholt have a fistula? . . . If he had one, it was undiagnosed."). Dr. Chariker testified that nowhere in Mr. Aderholt's entire medical record, which was admitted into evidence, was it ever "suggested by any physician, attending, resident, intern, nurse, any hospital care worker, that Mr. Aderholt had a fistula." *See* Tr. Trans. at 2085; Ex. P-1453.

Dr. Chariker also explained that the injuries to Mr. Aderholt's pancreas were being managed separately from his abdominal wound. He stated that "there is actually a tube or a duct in the pancreas. If that had been injured or opened, that would create a lot of drainage creating a pancreatico fistula -- cutaneous fistula. We didn't see that. But it did create digestive breakdown or tissue death in that area and we drained it with a separate wound that was not connected to the abdominal wound. There were two separate injuries that we treated and we treated in two separate ways." Tr. Trans. at 2085. Even KCI's expert, Dr. Orgill, admitted that a patient could have both a fistula and a wound at the same time. *See* Tr. Trans. at 2790. Therefore, while the Chariker-Jeter closed suction drainage system's primary function might be to treat fistula, it is clear that it is also used to heal wounds as defined by the Court.

Accordingly, the Chariker-Jeter references teach a method for healing wounds that consists of inserting a screen means into a wound, sealing the wound with an adhesive film, and connecting the screen means to a vacuum source using a tube. Although, there are differences between the Chariker-Jeter system and the patents in suit, they are not of such a degree that the Court should completely disregard the similarities of the Chariker-Jeter prior art in its obviousness analysis.

However, even if the Court were to disregard the Chariker-Jeter prior art in its obviousness determination, the Court finds that in light of the remaining prior art, it is clear that the practice of using vacuum suction, tubing, a sealant, and foam to facilitate the healing

of wound and the success of such methods was already well known when the asserted claims were patented. As stated above, the Bagautdinov references alone disclose placing foam in a wound, sealing the wound, connecting a vacuum pump through the seal to the foam, and using negative pressure to heal the wound. The most significant difference between the Bagautdinov method and the asserted claims is in the Bagautdinov method of sealing the wound. But when the Bagautdinov method is combined with the method for sealing a wound disclosed in the Zamierowski prior art, it is clear that the asserted claims would have been obvious to a person having ordinary skill in the art at the time the patents in suit were granted.

Even if there are additional differences between the prior art and the asserted claims, the Court finds that any such minimal variations would have been apparent to one having ordinary skill in the art to adopt. Accordingly, after reviewing the prior art as a whole, the Court finds that after considering the primary obviousness factors the evidence is clear and convincing that there is no legally sufficient basis on the record to conclude that all asserted claims of the patents in suit were not obvious.

C. Secondary Considerations

The Federal Circuit has held that "secondary considerations, when present, must be considered in determining obviousness." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) ("[E]vidence of secondary consideration may often be the most probative and cogent

evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art."). Originally, three factors were regarded as secondary considerations: commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). Since then, several additional factors have been taken into account by the Federal Circuit, including: copying by others, praise of the invention, unexpected results, disbelief of experts, general skepticism of those in the art, commercial acquiescence, and simultaneous development.[6]

The jury found that Plaintiffs established the following secondary considerations for all of the claims asserted except Claims 116 and 121 of the '651 patent: commercial success, long-felt need, copying of the invention, unexpected and superior results, praise of the invention, and unexpected results. While Plaintiffs did present ample evidence of the success of the V.A.C. product and the other secondary considerations tending to show non-obviousness, the Court is not convinced that they overcome the strong case of obviousness established by the teachings of the prior art. *See Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009) ("[A] strong prima facie obviousness showing may stand even in the

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[6] *See Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1379-80 (Fed. Cir. 2000); *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998); *Advanced Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1285-85 (Fed. Cir. 2000); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1144 (Fed. Cir. 1985); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

face of considerable evidence of secondary considerations.").

The Court does not doubt the success of the V.A.C. System or the inventors' belief in the novelty of their wound healing method. Neither is there evidence that the inventors had ever heard of the methods described in the prior art when they sought their patents. However, obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art and access to "all prior art references in the field of the invention." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (citing 35 U.S.C. § 103(a); *In re Carlson*, 983 F.2d 1032, 1038 (Fed. Cir. 1993)). As stated above, the Bagautdinov references, while they may not have been easily accessible to the inventors, disclose almost all of the claims asserted. In areas where the claims are slightly different from Bagautdinov, such as the type of sealant used, other prior art, like the Zamierowski reference, clearly discloses that structure.

Additionally, even if the Court assumes that the Chariker-Jeter prior art was limited to treating fistulae as Plaintiffs' consistently argue, the references are evidence that a system with basically the same components as those in the patents in suit was being used to heal the body before the patents were granted. Additionally, the Chariker-Jeter public use on Mr. Aderholt is evidence that a person skilled the art would have been motivated to use such a system, even if it was primarily used on patients with fistulae, to close a large open wound not complicated by a fistula.

Consequently, after considering the record as a whole, the Court finds by clear and convincing evidence that the claims asserted in the patents in suit are invalid as obvious.

Conclusion

For the reasons stated above, S&N's Motion for Judgment as a Matter of Law of Invalidity for Obviousness (Docket No. 504) is GRANTED. Accordingly, judgment will be entered in favor of Defendants.

It is so Ordered.

Signed this 18th day of October, 2010.

Royal Furgeson
Senior United States District Judge